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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,076	12/31/2003	Sidney N. Wolfe	PP16022.017 (35784/271881	2260

45853 7590 10/18/2007

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INTELLECTUAL PROPERTY - R338
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EXAMINER	
HISSONG, BRUCE D	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/750,076	Applicant(s) WOLFE ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	Art Unit 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 July 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2,4-8,10-16,18-22,24-30 and 32*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 5. Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112-1st paragraph (enablement and written description) for claims 1-2, 4-6, 8, 10-14, 16, 18-20, 22, 24-27, 30, 32-34.

Continuation of 13. Other: Rejection of claims 1-2, 4-6, 8, 10-14, 16, 18-20, 22, 24-27, 30, and 32-34 under 35 U.S.C, 112, first paragraph, regarding lack of enablement and written description for methods utilizing fragments or variants of IFN-b polypeptides, as set forth on pages 2-4 of the office action mailed on 4/30/2007, is withdrawn in response to Applicants amendments to the claims to recite "biologically active" IFN-b, and Applicants arguments that variants of IFN-b were known in the art at the time the present application was filed, and the art teaches how to make and use biologically active variants of IFN-b. The Applicants also provide a listing of various IFN-b sequences showing their precent identity to SEQ ID NO: 1. In light of Applicants' amendments to the claims, the recited list of IFN-b sequences, and Applicants arguments, the enablement and written description rejections over IFN-b fragments and variants with withdrawn.

Claims 7, 15, 21, 29, and 35 remain rejected under 35 U.S.C. 112, 1st paragraph, regarding lack of enablement and written description for all IFN-b polypeptides with at least 80% identity to SEQ ID NO: 1, as set forth on pages 2-4 of the office action mailed on 4/30/2007. Applicants arguments regarding IFN-b fragments and variants is discussed above. However, it is noted that the claims are drawn to any polypeptide with 80% identity to SEQ ID NO: 1, with no functional limitation other than said polypeptide be "biologically active". Although the several IFN-b variants are known in the art and disclosed in the instant specification, the specification does not teach how to make, and then use, all possible polypeptides having 80% identity to the sequence of SEQ ID NO: 1 as the only structural or functional limitation. Additionally, the listing of various IFN-b sequences in the Applicants response is insufficient to adequately describe the claimed genus of polypeptides, which read on all possible polypeptides having 80% identity to SEQ ID NO: 1, regardless of whether or not said polypeptides exhibit biological activity associated with IFN-b (e.g. antiviral, antiproliferative, immunodulatory activities)

Claims 8, 10-16, 18-27, 24-30, and 32-35 remain rejected under 35 U.S.C. 103(a) as being obvious in view of the combination of Arora et al and Dorin et al, as set forth on pages 5-7 of the office action mailed on 4/30/2007. In the response received on 7/2/2007, the Applicants argue that the subject matter of the instant claims is not obvious in view of the cited combination of art because neither Arora nor Dorin provide any helpful insight as to selection of the claimed pH ranges or guanadine HCl concentration. Therefore, one of ordinary skill in the art would not be provided with the necessary guidance to have a reasonable expectation of success in combining Arora with Dorin to arrive at the Applicants' claimed invention. These arguments have been fully considered and are not persuasive. As stated in the previous office action, the combination of Arora and Dorin teaches the general conditions for isolation of polypeptides (Arora), and a specific polypeptide, which is identical to SEQ ID NO: 1 and can be isolated by the methods of Arora. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 454, 105 USPQ 223, 235, (CCPA 1955). Furthermore, neither Arora nor Dorin teach away from the claimed pH ranges or guandidine concentrations, and Dorin specifically teaches pH optimization of IFN-b compositions for optimizing IFN-b polypeptide longevity and ease of administration to subjects (column 13, lines 48-50). Thus, in the absence of evidence that the claims encompass the only effective pH ranges, one of ordianry skill in the art would have both the motivation and the abilty to optimize the pH ranges and guandinine concentrations in order to practice the claimed methods.

Claims 1-2 and 4-7 remain rejected under 35 U.S.C. 103(a) as being obvious in view of the combination of van Oss, Arora et al, and Dorin et al, as set forth on page 7 of the office action mailed on 4/30/2007. The Applicants' arguments regarding the teachings of Arora and Dorin are discussed above. The Applicants further contend that the disclosure of van Oss, which teaches methods of protein isolation using ethanol precipitation, do not remedy the deficiencies of Arora and Dorin regarding critical variables such as the pH and guanidine concentrations in the claimed methods. These arguments have been fully considered and are not persuasive. The combination of van Oss, Arora, and Dorin teach the general conditions for the claimed methods of isolation of IFN-b polypeptides, namely precipation of IFN-b polypeptides with ethanol, followed by denaturation with guanidine HCl and subsequent renaturation. As stated above, neither Arora nor Dorin teach away from the claimed pH ranges or guanidine concentrations, and therefore one of ordinary skill in the art would have both the motivation and the ability to optimize the pH and guanidine concentrations in order to practice the claimed methods..